

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/553,108	10/12/2005	Nobuo Mochizuki	20241/0203481-US0	8647	
7278 DARBY & DA	7590 11/16/2007	EXAMINER			
P.O. BOX 770		HAVLIN, ROBERT H			
Church Street New York, NY			ART UNIT	PAPER NUMBER	
11011 10111,111	10000 0770		1626		
			MAIL DATE	DELIVERY MODE	
			11/16/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/553,108	MOCHIZUKI ET AL.				
Office Action Summary	Examiner	Art Unit				
	Robert Havlin	1626				
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address				
Period for Reply		O) OD TUUDTY (OO) DAYO				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim viil apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	I. lely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status	•					
1) Responsive to communication(s) filed on 19 Se	eptember 2007.					
· —	☐ This action is FINAL . 2b) ☐ This action is non-final.					
3) Since this application is in condition for allowar						
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	93 O.G. 213.				
Disposition of Claims	•	•				
4) Claim(s) 1-13 is/are pending in the application.	•					
4a) Of the above claim(s) 4 and 7-12 is/are with	ndrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-3,5,6 and 13</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	r election requirement.					
Application Papers						
9) The specification is objected to by the Examine	r					
10) The drawing(s) filed on is/are: a) acce		Examiner.				
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correct						
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a))-(d) or (f).				
a)⊠ All b)□ Some * c)□ None of:	,					
1. Certified copies of the priority documents	s have been received.					
2. Certified copies of the priority documents	s have been received in Applicati	on No				
3. Copies of the certified copies of the prior		ed in this National Stage				
application from the International Bureau						
* See the attached detailed Office action for a list	of the certified copies not receive	ed.				
		•				
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary Paper No(s)/Mail Da					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	5) Notice of Informal P					

Art Unit: 1626

DETAILED ACTION

Status of the claims: Claims 1-13 are currently pending. Claim 13 was added in a preliminary amendment.

Priority: This application is a 371 of PCT/JP04/05237 04/13/2004 and claims foreign priority to JAPAN 2003-109667 (04/14/2003) and JAPAN 2004-023032 (01/30/2004).

IDS: The IDS dated 10/13/2005 and 1/9/2006 were considered.

Election/Restrictions

1. Applicant correctly points out that there was a typo in the restriction requirement omitting claim 13 from group I. Applicant's election without traverse of Group I (claims 1-3, 5, 6, and 13) in the reply filed on 9/19/07 is acknowledged.

Applicant also elected the following species and claims 1-3, 5, 6, and 13 read thereupon:

Compound 37 which is described in Table 1 as: N-C0-B-Z, wherein the variables are defines: A is 4-a2; B is -; and Z is h1. These variables are further defined such that:

Art Unit: 1626

As detailed below, the elected species was unpatentable and in accordance with the election of species practice described in the requirement for restriction, subject matter not reading on the elected species is hereby withdrawn.

Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1-3, 5, 6, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umeda et al. (US 6,342,516 or "'516" patent) in view of Hansch et al. (Substituent Constants for Correlation Analysis in Chemistry and Biology, (1979), Wiley, pages 1-63).

The claims are drawn to the elected species.

Prior art teachings

The <u>'516 patent</u> teaches numerous compounds as drugs with a therapeutic use including as an anti-oxidant. The patent discloses numerous compounds structurally related to those shown in table 3 below:

Art Unit: 1626

US 6,342,516 B1

59

TABLE 3

Compound No.	A*	В	Υ .	Z	Physical Constant [] m.p. ° C.
3-1	4-81	_	_	h,	[229-231]
3-2	4-a1	_	_	h ₂	[219-222]
3-3	4-a1	_	_	h ₃	[220-222]
3-4	4-a1	CH ₂	_	h,	[126-129]
3-5	4-a1	CH ₂ CH ₂	_	h,	[112-114]
3-6	4-a1	CH(Me)CH ₂	_	h,	[137-142]
3-7	4-a1	CH ₂	N(Me)C(=O)	h,	amorphous&NMR1
3-8	- 4-a1	(CH ₂) ₅	NHC(=0)	h,	[194-196]
3-9	4-a1		_ ` `	h.	[232-233]
3-10	4-a1	CH,CH,	_	h.	[110-113]
3-11	4-a1	CH ₂ CH ₂	_	ho	[104-107]
3-12	4-81	(CH ₂) ₄		h ₄	[211-214]
3-13	4-a1		- ,	b _o	[192-193]
3-14	4-a1	-	_ `	ha	[204-206]
3-15	4-a1	CH=CH	_	h ₄	[143-148]
3-16	4-81	CH = CH = CH = CH		h4	[245-248]
3-17	4-a1	(CH ₂) ₄	_	h,	[211–214]
3-18	4-n1		_	h ₁₂	[184-187]
3-19 ·	4-a2		_	h _o	[203-206]
3-20	4-81	<u>.</u>		h_7	amorphous&NMR2
3-21	3-a1	_		h,	[207-210]
3-22	2-a1	_	****	h,	[191-196]
3-23	4-a3	_	_	h,	[203-206]
3-24	4-a5		–	h,	[166-167]
3-25	4-a2	_	_	h,	[215-218] '
3-26	4-a2	CH ₂ CH ₂	_	ho	[195-196]
3-27	4-a1	(CH ₂) ₂ CH(Ph)		h ₁₄	amorphous&NMR3
3-28	4-a1	(CH ₂) ₅ CH(Ph)	_	h ₁₄	amorphous&NMR4
3-29	4-a1	(CH ₂) ₄	_	b14	[140-143]
3-30	4-a1	CH ₂ CH ₂	_	h14	[145-150]

Representing together the substitution site to the phenyl group. & represents the NMR data are presented in Table 5.

Specifically, the compound No. "3-19" as described in Table 3 where: a2=1H-pyrazol-5-

$$\begin{array}{c} \text{CH}_3 \\ \text{OCOCH}_3 \\ \text{CH}_3 \end{array}$$
 vI; and h9 =

Hansch et al. teaches a well-known in the art methodology for arriving at the optimum drug based on making substitutions on aromatic rings with different substituents. The methodology uses a quantitative structure-activity relationship (QSAR) to guide a practitioner in a non-random manner to an optimum drug target.

Art Unit: 1626

Specifically, in Table VI-I on pages 49-50 the reference teaches "well characterized aromatic substituents" including –NH2 and –OCOCH3.

Differences between the prior art and the claims

The difference between the prior art and the elected species is the particular

$$H_3C \xrightarrow{CH_3} H_2$$

$$H_3C \xrightarrow{CH_3} CH_3$$

substitution on the aromatic ring of the "Z" variable,

Where

the elected species has –NH2, the '516 patent has –OCOCH3.

Finding of prima facie obviousness: rationale and motivation

One of ordinary skill in the art had motivation to arrive at the elected species because of general knowledge about optimizing drug targets and the teachings of Hansch et al. to arrive at the optimum drug. In addition, the prior art and the instant invention are in the identical field of endeavor and are used for the same purpose of anti-oxidant. As evidenced by the teachings of the '516 patent on columns 17 and 18 the substitutions on the aromatic ring were a prime target for optimization. Furthermore, the reference also teaches the –OH substitutuent at the site in question thereby indicating that the substitution at this site was readily alterable while maintaining the function of the compound. Therefore, one of ordinary skill in the art would have found it obvious to make a substitution of –NH2 on compound 3-19 in the '516 patent and arrive at the instant invention based on the QSAR methodology well-known in the art and exemplified by Hansch et al.

Art Unit: 1626

Claim Objections

Formula 1 is not depicted in the amended claim 1.

Conclusion

No claims are in condition for allowance.

<u>Correspondence</u>

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert Havlin Examiner RH

KAMAL A. SAZED, F PRIMARY EXAM